Appendix: 17

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From: **Bianchi, Patricia A.**
Subject: Outside Leveraging

I thought I would put some of my **preliminary thoughts** on paper on what mechanisms maybe possible to accomplish the outside leveraging projects OSB has been discussing.

- **MDR Network Project**
  Goal: Increased analysis of complaint files and MDR files (80,000 annually) to detect risks
  Proposed Partner:
  Partnering Suggestions: a CRADA
  Non Leveraging options: provide a government liaison to a colloquia set up by the RAPS group, hold grassroots meetings or workshops (with or without a co-sponsors)

- **Device Use Error Reduction Report Project**
  Goal: Encourage reduction of "use error" by rewarding manufacturers who work to reduce this type of error
  Proposed Partner: voluntary program patterned after EPS's "33/50" Program
  Next Steps: Talk with Chris Tirpak of EPA and find out how they handled OMB clearance issues and FOI disclosures

- **Malfunction Reporting Project**
  Goal: Eliminate excess reporting (50,000 per annum) by further defining "likely to cause serious injury or death."
  Proposed Partner:
  Partnering Suggestions: Advertise for CRADA partners
  Question: Could this project be combined with the MDR Network project?

- **User Facility Reporting Project**
  Goal: Obtain from user facilities anonymous reports of "root cause analyses" of medical device failures (Users now prepare these analyses to meet the requirements of JCAHO.
  Proposed Partner: AMA's Patient Safety Foundation or ECRI
  Non-leveraging options: ask for this information as part of our Sentinel Program or contract with a firm such as CODA -- the current contractor for Devicenet.

- **Internet based Medical Device Scientific Information (MEDESCI) Exchange Project**
  Goal: Provide a web-based open forum for the rapid exchange of scientific and clinical information
  Proposed Partners: American Heart Association, "British Heart Association", American College of Cardiology, NIH/NHLBI, AMA, ECRI, HIMA

Partnering Suggestions: Advertise for CRADA partners and jointly work out who will be responsible for fronting the effort, the content of MEDESCI, and accuracy of the information archived.
Non-leveraging options: provide information to a privately funded website appending "hot links" to CDRH's internet.

- **Supplement NCHS's National Health Interview Survey Project**
  Goal: Use industry funds to add questions to the next National Health Interview Survey; these questions would deal with the prevalence of crucial medical devices, and the use of devices in the home health care setting.
  Proposed Partners: Device firms and NCHS
  Partnering Suggestions: A joint CRADA between industry and the government (CDRH and NCHS)

- **Establish CDC as a 3rd Party in Post Market Surveillance Project**
  Goal: Notify firms required to do Postmarket Studies that CDC is a possible source for certain PM studies
  Proposed: Device firms and CDC
  Partnering Suggestion: MOU with CDC indicating what device areas they are interested in studying. This information could be communicated to those device firms wishing to use a government source, so they could make the appropriate arrangements with CDC.

Suggestion: Since many of options shown above deal with CRADAs, would you like me to pull together a short presentation on CRADAs? I would invite Bea Droke (Executive Sec of the CRADA Board) and Michelle Chenault (CDRH's FTTA Research Coordinator) so we get off to a good start. I would also bring slides from a presentation that Dr. Burlington made to HIMA on CRADAs and also a model CRADA agreement developed by Linda Horton to solicit partners for global harmonization activities. Before the meeting, participants may want to review the information at Tab 13 in your Outside Leveraging Seminar handbook or visit FDA's website:
http://www.fda.gov/ofacs/partnerships

Caution: Since some of these projects will ultimate end in rule making (e.g., Malfunction Report) we need to be careful how we develop the actual agreements. You may want to get Joe Sheehan's input on this issue.